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Apelon Response to Health IT Standards Committee Clinical Operations Working Group Questions on Vocabulary Requirements

Apelon is honored to provide input to the Vocabulary Task Force of the Office of the National Coordinator's Health IT Standards Committee regarding infrastructure considerations to provide a consistent and predictable one-stop shop for vocabularies, value sets, and subsets.

Apelon has been a leader in the development and provision of health care terminology infrastructure as a way of distributing terminology content for many years. Our open source Distributed Terminology System (DTS) provides an integrated set of components for terminology services in distributed application environments that support both national and international data standards as well as local vocabularies. This infrastructure has been extended to incorporate standard terminology service interfaces, namely, HL7's Common Terminology Services (CTS) standard. The linking of terminology service platforms to standard terminology service interfaces provides a beginning towards developing the necessary components to support comparable and interoperable health information through shared infrastructures.

Apelon has worked with many users on the complex activity of developing and deploying terminology service infrastructures to support their requirements of sharing and managing terminologies across their organization and with other organizations. We have also worked with users to develop a methodology we call Terminology Asset Management℠ (TAM), which defines best practices for realizing the benefits of terminologies and terminology services.

Apelon is in agreement with the focus and direction of HHS and the ONC that semantic interoperability is a crucial element of the value proposition for deploying health care information technology. Semantic interoperability using structured terminology can only be assured if the mechanism used to access and share this content is equally consistent.

Answers to questions are informed by Apelon's broad and deep experience with terminologies, including development of our popular open source Distributed Terminology System (DTS) software, provision of subscription-based terminology content and consulting services to our diverse client base, and leadership in industry standards efforts, including the HL7/OMG Common Terminology Services (CTS) 2 specifications now in progress.

1. **What are the requirements for a centralized infrastructure to implement "one-stop shopping" for obtaining value sets, subsets, and vocabularies for meaningful use?**

In a one-stop shop, all vocabularies, subsets and value sets (collectively referred to here as vocabulary artifacts) must of course be clearly identified, complete, correct, and up to date. All relevant versions of artifacts must be downloadable in full and must remain available indefinitely. Precise documentation must be available for all download format(s). To facilitate meaningful use, metadata must unambiguously associate (or bind) each version of each artifact with corresponding meaningful use elements and as appropriate, versions thereof. An intuitive graphical user interface is required to enable users to locate artifacts via navigation and search (including by their application to meaningful use). Standard terminology services are required for consistent programmatic access to vocabulary artifacts from a one-stop shop for meaningful use along with local vocabulary artifacts.

2. Which requirements or functionalities are urgent, i.e., absolutely required to support "meaningful use"? Which would be most useful immediately? What would be a staged approach over time to get to the desired end state?

Beyond the immediate requirements noted above, future directions might include (among many others):

- Delivery of all artifacts in accord with a single consensus standard content model and corresponding data format
- Standard terminology service access to artifacts via an implementation of Common Terminology Services 2 specifications, now under development through the partnership of HL7 and OMG
- Placement of vocabulary artifacts in a "shopping cart" for review and bulk download
- Persistent "shopping lists" to facilitate acquisition of new versions of vocabulary artifacts as available
- Subscription for notifications about updates of interest

3. Where are you using value sets and subsets? For what domains? How many value sets and subsets?

Apelon customers span the Healthcare IT community, including providers, payers, pharmaceutical and biotechnology companies, government agencies, software vendors, integrators, publishers, research and standards development organizations, etc. Consequently, they use value sets for rather diverse purposes. In addition, the Apelon Consulting Group develops and/or uses them extensively for client engagements involving interoperability, decision support, quality measure development, etc. In our experience, hundreds of value sets and subsets are required for meaningful use and other national needs.

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4. **In your experience with creating, disseminating, updating and/or using value sets, subsets, and entire vocabularies, what works and what does not work?**

   Defining and following through on a rigorous overall process with knowledgeable and skilled personnel is essential. On the technology side, we have found the visual appeal of intuitive yet flexible and powerful GUI interfaces invaluable, whether for authoring vocabularies or extensional (enumerated) and intensional (descriptive; rule based) subsets/value sets, reviewing them, perceiving them in relation to their underlying vocabularies, specializing, importing, exporting, etc. Likewise, our full featured Terminology Query Language (with full subset/value set features), in the spirit of SQL for databases, has been extremely useful. TQL enables users to declaratively retrieve terminology artifacts and update custom/local terminology artifacts, sometimes in complex ways, without resorting to programming or tedious repetition of manual operations.

5. **What human resources does it take to implement and manage value sets, subsets, and entire vocabularies? Informaticists? Clinicians? IT people? How are you organized?**

   Apelon has a focused team to deliver vocabulary resources, led by our Director for Content in collaboration with our Chief Medical Officer, engineering group and consulting group. Participants include IT personnel with database, software and QA skills, along with informaticists and clinicians. Importantly, team members are also seasoned experts at working with vocabulary artifacts, experienced with the demands of fielded terminology solutions, as well as major contributors and participants in relevant standards organizations.

6. **What national resources and services could be leveraged to reduce the level of effort required for local implementations ? What is the irreducible minimum of local work at an implementation site, or within an organization or system?**

   A one-stop shopping solution will be a truly great start. Local sites or organizations and those responsible for local systems will inevitably want to use only a portion of the available vocabulary artifacts. Moreover, they will only want to use a portion of a specific artifact; e.g., a local practice will want to use some but not all members of a meaningful use value set for clinical findings. Such local choices will have to be implemented locally, assisted by a set of localization tools supporting subsetting, mapping, etc. Also, given that we are in the early stages of promoting consistent use of terminology artifacts within complex systems, the ability to provide a forum for dialogue on the use of the artifacts, request modifications and enhancements, describe implementation experiences, and provide overall support will be critical. In today's world the value of social exchange cannot be overstated.

7. **What is your maintenance process? How do you manage updates?**

We track and gather content releases from disparate sources. For a new source, we study the native content model, determine a full and faithful rendition of the content according to our common DTS data model, develop a repeatable method for rendering the content in DTS using that common model, implement the method, validate the results for completeness and correctness, and distribute them to clients. For an updated source, we repeat the process starting with rendition in DTS, but additionally compute, validate and distribute incremental updates that can be applied to an earlier version of the source.

8. What metadata do you maintain and how do you maintain versioning?

Out of the box, DTS today represents a fixed set of metadata such as names and identifiers, version identifiers and dates, responsible authorities, etc. We anticipate implementation of a CTS 2 interface for DTS and expect that the future OMG standard CTS 2 Platform Independent Model will provide for fully flexible metadata. This flexible metadata model, coupled with a single consensus standard content model, will over time provide consistency and assist maintenance of cross code system metadata elements. Terminology sources generally publish only full versions in succession. We have developed software to compare versions and compute the precise differences so we can deliver relatively small incremental updates across versions. That also allows us to report on localized content such as local mapping elements that would be impacted when a new version is adopted so potential issues can be addressed in advance.

9. Is there a difference between versioning for clinical documentation vs. versioning for reported measures, i.e., when do you go live with a change in the EHR vs. when do you use the new version for measures?

The first priority is to implement new versions in the EHR based on regulatory requirements and best practices for patient care. Measures can incorporate new versions later, but must be updated before they can be considered valid for time periods including new EHR version usage, in which case the measures themselves should be versioned. Measures require particular attention when the period measured spans multiple versions of referenced terminology artifacts.

10. How do you manage versioning in clinical decision support vs. changes in value sets?

In our view, management of relationships between versions of clinical decision support artifacts such as rules and versions of vocabulary artifacts that they reference is conceptually similar to versioning for clinical documentation vs. reported measures. Versioning of a CDS artifact entails the versions of all “versionable” components and it will

be up to the user to decide if moving between versions of any component part has an impact on the local implementation. However, it should be clear that when using different versions of the component parts (a different version of the value set or the rules), the dependent CDS (such as a quality measure) could result in a different outcome. Therefore it should be the responsibility of the measure steward to assess each of these version changes and declare if component version changes result in CDS (quality measure) changes (hence a new version of the quality measure).

11. How does an application know which value set is for which purpose? How is the specific context for a value set maintained at the message data element level of specificity? How is the English language intent of the value set context documented and maintained?

This requires complete and current metadata, created and maintained in accord with an appropriate metadata model that precisely captures purposes and/or contexts where value sets apply. Apelon has developed such a metadata model, implemented it using DTS, and deployed it for use in interoperability solutions. English language intent can be accommodated similarly.

12. What are lessons learned about web links vs. storage of the vocabulary or other artifact in a physical repository?

Assuming the question concerns web links to authoritative non-local sources, when a local application such as an EMR, HIE portal, or PHR truly requires reliable access, web links are no substitute for local (cached) storage. However, local storage must be appropriately synchronized with updates to the authoritative source.

13. How do you manage distribution of updates to multiple sites?

Apelon maintains comprehensive vocabulary content using our own DTS systems. Clients subscribe for content of interest, receive email notification when new versions are available, then access updated content via the Web. They can choose full and/or incremental updates at will.

(The CTS 2 Service Functional Model and draft Platform Independent Model submissions provide for a similar process.)

14. Where is local customization appropriate and how much customization is acceptable?

See the response to question 6. Assuming basic compliance with regulatory/meaningful use requirements, a greater degree of local customization may yield applications that are better

tailored for local users, resulting in better/faster/cheaper application usage, at higher local cost for maintaining those local customizations in the face of updates to underlying standards and changes to regulations/meaningful use requirements. The best tradeoff depends on local circumstances. Expert guidance from seasoned terminologists can assist in making the determination.

15. How do you manage distribution of updates with local variations and optionality? Unique subsets? Local mappings?

DTS detects and reports the impact of new versions on localizations. GUI interfaces allow local users to review and resolve the impact before migrating to a new version.

16. What has to be local in an EHR implementation vs. what can be external in a vocabulary repository?

Vocabulary servers implement comprehensive vocabulary services for both human users and software applications using suitable vocabulary repositories. We strongly believe that all vocabulary artifacts for an EHR implementation should be acquired, reviewed, localized, maintained, etc., in the context of a vocabulary server using vocabulary server applications such as vocabulary editors and browsers. For run time use, an EHR system can reasonably access vocabulary artifacts via vocabulary server(s), though it is also often appropriate to export vocabulary artifacts from the vocabulary server for direct access within the EHR system.

17. What functions are required that users have not yet appreciated?

Initial completion of one-stop shopping is just the beginning for users. Long-term acquisition and use of vocabularies, value sets and subsets, including initial versions and subsequent updates, will require a comprehensive, integrated and sustainably effective long term process, along with capable supporting personnel and tools, to achieve proper implementation in applications. Leading edge users appreciate that, at least in general, but many others have yet to confront the challenges involved. Apelon's Terminology Asset Management^{SM} (TAM) methodology highlights relevant functionality, some of which can be provided or facilitated by a one-stop shop for meaningful use vocabulary artifacts. Examples include functions to compute, report on, and remediate effects of updates to standards on localized content.